

United States Senate

April 6, 2020

Secretary Alex Azar
U.S. Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Azar:

Americans across the country are practicing social distancing and staying home to reduce the risk of coronavirus to themselves and others. But these necessary steps have come at a steep economic and personal cost with businesses closing and workers losing their jobs. The best path to national recovery requires that people return to work when it is safe to do so. Therefore, it is paramount that we quickly disseminate ways for individuals to know if they have contracted coronavirus and recovered and for health and government officials to understand the degree of recovery in their communities.

I accordingly urge you to use your current authority to direct the Strategic National Stockpile (“SNS”) to begin as soon as possible the purchase and distribution of serological tests that can determine whether an individual previously contracted coronavirus.

In the Coronavirus Aid, Relief, and Economic Security (“CARES”) Act, Congress appropriated billions of dollars for you to procure medical supplies to combat the coronavirus outbreak, including supplies for the “administration of drugs, vaccines, and other biological products, medical devices, and diagnostic tests.” *See* CARES Act § 3102. Although the stockpile already includes diagnostic tests for coronavirus (sometimes called antigen tests), it does not include a sufficient number of serological tests. These are distinct and often serve an entirely different purpose. As you know, serological tests analyze a blood sample for the presence of antibodies to the coronavirus, and a positive test result usually means the patient contracted coronavirus previously and is recovering or has recovered from the virus.

Without a sufficient level of serological tests, we cannot understand the full scope of the coronavirus pandemic, and we cannot identify if and when parts of the country approach herd immunity. Only once we identify coronavirus survivors can they donate blood to be used in studies and potential cures involving convalescent plasma therapy. Put simply, without serological tests, it will be exceedingly difficult for individuals and government officials to determine how best to respond to the pandemic.

That is why we need to ensure that serological tests are mass produced. Currently, these tests are not widely available, even though over fifty manufacturers and laboratories have notified the Food and Drug Administration (“FDA”) that they can offer serological tests. And while I am encouraged by the FDA’s decision on April 1 to grant an emergency-use authorization for one company’s serological test, this single authorization is not sufficient to enable producers to meet our country’s urgent need for these tests.

To encourage needed mass production, HHS should purchase for the SNS a large quantity of these tests. For comparison, the United Kingdom—a country with one-fifth of the population of the United States—recently ordered 3.5 million serological tests for private use. A purchase along this magnitude would encourage mass production by sending a clear signal to commercial manufacturers and laboratories that there is strong and growing demand for these tests. Moreover, it would help stabilize the supply chain against hoarding and price-gouging.

America's recovery from this virus depends on citizens eventually returning to work—once it is safe. Serological testing is a critical way to quickly and accurately assess coronavirus risk. HHS should use its existing authority and funding under the CARES Act to purchase these tests to accelerate their production and distribution around the country.

Sincerely,



Ted Cruz